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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,886	06/26/2000	Roy Sullivan	10546/56701	2146

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FAY KAPLUN & MARCIN, LLP
150 BROADWAY, STE 702
NEW YORK, NY 10038

EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/603,886	Applicant(s) SULLIVAN, ROY	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 33-42 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 33-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "naturally occurring body orifice" lacks antecedent basis in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-36,40 rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin Jr. in view of Murphy-Chutorian. McGuckin Jr. disclose a tissue resectioning system including a resection head 12 mounted at the distal end of a elongate flexible body 16 and diagnostic imager for providing guidance of the resectioning head and a control unit 14. The imager can be CT, MRI, Fluoroscopy etc. (see column 3, lines 58-65). McGuckin Jr. fails to disclose the use of a marker. It is old and well known in the art to place a detectable marker on a catheter/tubular body inserted in a patient's body such that the catheter's/tubular body position can be easily located using an imaging device sensitive to the type of marker used. An example of such is seen in Murphy-Chutorian which shows a resecting device in combination with an image detectable marker. The image along with the marker is then displayed to show the operator where it is positioned. It would have been obvious to one skilled in the art to have modified McGuckin Jr. such that it includes a detectable marker which when imaged enables the operator to visualize the location of the elongate flexible body in the body.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin Jr. in view of Murphy-Chutorian as applied to claim 33 above, and further in

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view of Osterholm. Osterholm discloses a medical system having a control device that will disable the system if the operation of such falls outside of the desired operating parameters. It would have been obvious to one skilled in the art to have further modified McGuckin Jr. such that it includes a means for disabling the system if the marker indicated that the resection device is oriented outside the defined region of tissue in order to ensure that no harm comes to the patient if the resection device moves out of the region of interest.

Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin Jr. in view of Murphy-Chutorian as applied to claim 33 above, and further in view of Aida et al. Aida et al disclose a system having a control tissue therapy system that includes an alarm means to notify a user of a deviation from the treatment plan. The alarm can either be in the form of a visual or audio signal. It would have been obvious to one skilled in the art to have further modified McGuckin Jr. such that it includes an alarm means in order to ensure that no harm comes to the patient if the resection device moves out of the region of interest.

Claims 41,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin Jr. in view of Murphy-Chutorian as applied to claim 33 above, and further in view of Kreizman et al. McGuckin Jr. fails to disclose the use of an automatic control unit for controlling operation of the resectioning device and the specific manner in which the defined region is determined. Kreizman et al disclose a resectioning device having a control system that controls operation of the resection device by determining the defined region of tissue and moving the device to the desired location. It would have been obvious to one skilled in the art to have further modified McGuckin Jr. such that it includes a controller that will automatically determine the desired region of interest and move the resecting head to that location. The advantage of such is to eliminate the chance of operator error. In the absence of any showing of criticality or unexpected results, the manner in which the defined region of interested is determined would have been an obvious matter of design choice of known functional equivalents in the art.

Response to Arguments

Applicant's arguments filed January 7, 2005 have been fully considered but they are not persuasive. The examiner does not agree with the applicant regarding the term "naturally occurring orifice", therefore, such a term should be added to the specification if applicant insists on using it as part of the claim language. Applicant's comments regarding McGuckin, Jr. are not understood in view of column 3 of the reference which discloses that diagnostic imaging guidance such as CT scans, fluoroscopic imaging, MRI etc can be used with the medical resecting device. With regard to Murphy-Chutorian, the reference discloses that the tip of the device can include a marker such that the device can be located using a fluoroscope (see column 11, lines 58-62).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

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